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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/069,228	04/27/98	PLOWMAN G	234/118

022249
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HM12/0607

EXAMINER	
HOLLERAN, A	
ART UNIT	**PAPER NUMBER**
1642	12

DATE MAILED: 06/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/069,228	Plowman et al.
Examiner	**Group Art Unit**
Anne Holl ran	1642

☒ Responsive to communication(s) filed on *Jan. 19, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *2-5, 9, and 23-40* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☒ Claim(s) *2-5, 27, 29-34, and 37* is/are allowed.

☒ Claim(s) *9, 23-26, 28, 35, 36, and 38-40* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. This communication is responsive to the Amendment filed Jan. 19, 2000.

Claims 2-5, 9 and 23-40 are pending and examined on the merits.

Claim Rejections - 35 USC § 112

2. The rejection of Claims 2-7, 9 and 23-37 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 112

3. The rejection of Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the Applicant's amendment to claim 23.

Claim Rejections - 35 USC § 101

4. The rejection of Claims 9, 23, 24, 28 and 37 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is withdrawn in view of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 102

5. The rejection of Claims 2-7, 9, 27-33 under 35 U.S.C. 102(e) as being anticipated by either US Patent 5,614,609 ("Ibanez et al.,'609" filed 15 Nov 1994), US Patent 5,789,565 ("Ibanez et al,'565" effective US filing date 15 Nov 1994) or US Patent 5,811,245 (Ibanez et al,'245" effective US filing date 15 Nov 1994) is withdrawn in view of Applicant's amendments to the claims. However, these references are applied to new claims 38-40, see below.

6. The rejection of Claims 2, 3, 5-7, 9, 23, 24, and 32 under 35 U.S.C. 102(a) as being anticipated by Ryden et al (see page 30604, Ryden, M. et al., J. Biol. Chem. 271(48): 30603-30609, 1996 is withdrawn in view of Applicant's amendments to the claims.

The subject matter of Claims 2, 3, 5-7, 9, 23, 24, 29 and 32 have been discussed above. Ryden et al disclose the deduced amino acid sequence of ALK-7 and teach the cloning of the DNA encoding ALK-7 and the expression of the mRNA encoding ALK-7. The cDNA was isolated from rat brain. A PCR probe, degenerate primers encoding the region VAFKIF was disclosed. Cos cells were disclosed as host cells for the nucleic acid molecules encoding ALK-7.

Thus, Ryden et al disclose nucleic acid molecules and host cells which are the same as that claimed.

Claim Rejections - 35 USC § 103

7. The rejection of Claim 34 under 35 U.S.C. 103(a) as being unpatentable over either Ibanez et al., '609, Ibanez et al.,'565 or Ibanez et al,'245 in view of US Patent 5,168,050 (Hammonds, Jr. et al, US Patent 5,168,050, publication date 1 Dec. 1992) is withdrawn in view of Applicant's amendments to the claims.

New Rejections

8. Claims 23, 24 and 35 and dependent claims 9, 25, 26, 28 and 36 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for nucleotides consisting of nucleic acid sequences encoding for polypeptides consisting of specified regions of the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for nucleotides comprising nucleic acid sequences encoding polypeptides comprising the amino acid sequence of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 23 is drawn to isolated, purified or enriched nucleic acids comprising nucleotide sequences that encodes polypeptides comprising amino acid sequence as set forth in SEQ ID NO:

2 except that the amino acid sequence lacks one or more, but not all, of the following segments of amino acid residues: 1-25, 26-113, 114-493, 137-493 or 193-483 of SEQ ID NO: 2. Claim 24 is drawn to isolated, purified or enriched nucleic acids comprising nucleotide sequences that encode polypeptides comprising amino acids sequences of various domains of SEQ ID NO: 2. Thus, 24, like claim 23 reads on nucleic acid sequences encoding polypeptides comprising fragments of SEQ ID NO: 2. Claim 35 is drawn to polynucleotides encoding truncated polypeptides of SEQ ID NO: 2.

Because the claimed polynucleotides are drawn to polynucleotides that encode polypeptides, the usefulness of the claimed polynucleotides is, in part, tied to the usefulness of the polypeptides encoded. The usefulness of a polypeptide is defined by its biological function. The specification teaches that segments 1-25, 26-113, 114-136, 137-493 and 193-485 of SEQ ID NO: 2 correspond approximately to a "signal peptide", a "cysteine-rich extracellular region", a "transmembrane domain", a "cytoplasmic domain" and a "catalytic domain" of a protein with protein kinase activity. The biological function of the "catalytic domain" is understood to be that of catalyzing a kinase reaction when the "catalytic domain" is within the amino acid sequence of SEQ ID NO: 2. It is noted, however, that the specification does not provide teachings or guidance as to the identity of the substrates that are specific for SEQ ID NO: 2. In addition, the specification does not describe a peptide consisting of only the "catalytic domain" of SEQ ID NO: 2, but lacking all the rest of SEQ ID NO: 2, as possessing a biological function. Nor does the specification teach how, whether, or which parts of, the other segments of SEQ ID NO: 2 may

contribute to the biological function of the "catalytic domain". The lack of such teachings is important in this analysis because it is well known that the three dimensional structure of a polypeptide contributes greatly to its biological function and that the three dimensional structure of a polypeptide is determined by its amino acid sequence. Thus, one of skill in the art would not be know how to construct a useful polypeptide which comprises as its only identifiable region, the amino acid sequence that is the "catalytic domain" of SEQ ID NO: 2 and, therefore, one of skill in the art would not know how to construct a useful polynucleotide encoding such a polypeptide.

A similar analysis may be made for the other domains of SEQ ID NO: 2. However, in the case of the these domains where no biological function is described even when these domains are within the amino acid sequence of SEQ ID NO: 2, one of skill in the art would not know how to construct a useful polypeptide starting from these domains for two reasons: 1.) there is no biological function ascribed to these regions when they are within the amino acid sequence of SEQ ID NO: 2 and 2.) even if a biological function of the regions were known, one of skill in the art does not know how, whether or which parts of the other segments of SEQ ID NO: 2 may contribute to the biological function of each of these domains.

Polynucleotides may also be useful as probes for the detection of polynucleotides which hybridize to a probe. Within the scopes of claims 23, 24 and 35 are polynucleotides that may be used as probes for the detection of polynucleotides comprising polynucleotide sequences encoding for SEQ ID NO: 2. However, the usefulness of probes to detect polynucleotides is linked to biological function of the encoded proteins. This is because the reasons for screening

samples for polynucleotides that hybridize to a probe include, for example, the detection of diseases that correlate with the expression, or lack thereof, of a protein; or, for example, the detection of particular cell types that differentially express a protein of interest.

In the instant case, the specification describes polynucleotides encoding the polypeptide of SEQ ID NO: 2 which is asserted to be a protein kinase and thus has a biological function as a protein that phosphorylates its substrate. However, claims 23, 24 and 35 are drawn to polynucleotides which specifically do not encode polypeptides of SEQ ID NO: 2 because claims 23, 24 and 35 are drawn to polynucleotides encoding polypeptides lacking at least 1 regions of SEQ ID NO: 2 or are truncated. Thus, claims 23, 24 and 35 are drawn to polynucleotides which encode polypeptides which quite possibly do not have the biological function of the polypeptide of SEQ ID NO: 2. Thus, one of skill in the art would not know how to use the probes encompassed by the scope of claims 23, 24 and 35 for the detection of disease states and because one of skill in the art would not know the biological function of the encoded protein.

9. Claims 38-40 are rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 is drawn to a nucleic acid which encodes a "naturally occurring polypeptide". It is not clear what biological function or polypeptide structure is meant by a "naturally occurring

polypeptide". Thus, the phrase "naturally occurring polypeptide" does not provide adequate metes and bounds for the claimed polynucleotides.

10. Claims 38-40 are rejected under **35 U.S.C. 112, first paragraph**, because the specification, while being enabling for how to use polynucleotides comprising nucleic acids encoding the full length of SEQ ID NO:2, does not reasonably provide enablement for the full scope of the genus of polynucleotides encompassed by claims to polynucleotides which hybridize to polynucleotides comprising, or the full complement of, nucleic acids encoding the full length of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 38-40 are drawn to isolated, enriched or purified nucleic acid molecules which encode naturally occurring polypeptides and which hybridize to the nucleic acid molecule as defined in claim 2. The biological activity of the encoded protein is not recited in the claims. Thus, claims 38-40 are drawn to a genus of polynucleotides of varying size and encoding fragments or full length polypeptides of unknown biological function which will hybridize under stringent conditions (as recited in claims 38, 39 or 40) to a polynucleotide which comprises a nucleic acid sequence encoding a polypeptide comprising SEQ ID NO: 2. The specification discloses one fully described species, that of the polynucleotide of SEQ ID NO: 1 which comprises and open reading frame which encodes SEQ ID NO: 2. Hybridization language, while providing metes and bounds to the structures of the claimed polynucleotides, does not enable one

of skill in the art to know how to use a representative number of the claimed nucleic acids because the utility of the claimed polynucleotides is tied to the encoded proteins.

10. Claims 38-40 are rejected under 35 U.S.C. 102(e) as being anticipated by either US Patent 5,614,609 ("Ibanez et al.,'609" filed 15 Nov 1994), US Patent 5,789,565 ("Ibanez et al,'565" effective US filing date 15 Nov 1994) or US Patent 5,811,245 (Ibanez et al,'245" effective US filing date 15 Nov 1994).

Claims 38-40 are drawn to polynucleotides which hybridize under stringent conditions to polynucleotides encoding a polypeptide comprising the amino acid sequence of SEQ ID NO: 2. Ibanez et al.,'609, Ibanez et al,'565 or Ibanez et al,'245 disclose a polynucleotide which is almost 98 percent identical in nucleic acid sequence to a polynucleotide encoding SEQ ID NO: 2 (see enclosed sequence alignments). Thus, Ibanez et al disclose a polynucleotide which is the same as that claimed.

Conclusion

Claims 2-5, 27, 29-34 and 37 are allowable. Claims 9, 23-26, 28, 35, 36 and 38-40 are rejected.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

ALH

Anne L. Holleran
Patent Examiner
June 5, 2000

Yvonne Eyler

YVONNE EYLER, PH.D
PRIMARY EXAMINER